Ethical Rhetoric

ETHICAL RHETORIC: GENOMICS AND THE MORAL CONTENT OF UNESCO'S 'UNIVERSAL' DECLARATIONS

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(2008) 34(11) Journal of Medical Ethics e24

Abstract: Genomic research is an expanding and subversive field, leaking into various others, from environmental protection to food production to healthcare delivery, and in doing so, it is reshaping our relationship with them. The international community has issued various declaratory instruments aimed at the human genome and genomic research. These soft law instruments stress the special nature of genomics and our genetic heritage, and attempt to set limits on our activities with respect to same, as informed by the human rights paradigm. This paper examines the primary thrust and, more importantly, the joint value position of the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights, concluding that, though important legal instruments from the human rights paradigm, these instruments, or rather the values contained therein, must find a more influential hard law voice and a broader policy environment.

INTRODUCTION

Genomics can be characterised as a "transformative"[1] technology or practice insofar as it enables new forms of conduct (ie: permits new actions, objects and relationships) and serves as a crossroads for human identity and health, international science and commercialisation, and regulatory complexity and choice. As such, it is an ethically charged field that is most appropriately governed by instruments that are morally conscious and morally defensible.[2] Weakened social homogeneity, increased plurality, and reduced consensus around traditional morality,[3, 4] has resulted in the law emerging as a primary source of social integration.[5] Though the law need not be synonymous with morality,[6-8] it would be misguided to claim that the law (or legal instruments) should be divorced from morality. Indeed, it has long been recognised that the best law has a clearly identifiable if not explicitly moral foundation.[9-11]

Given the above, this paper considers the ethical within the legal. In particular, it considers two leading international legal instruments which explicitly address human genomic research – the Universal Declaration on the Human Genome and Human Rights (1997) [12] (UDHG), and the Universal Declaration on Bioethics and Human Rights (2005) [13] (UDB) – with a view to identifying and defining the

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core moral/social "values" claimed therein. Values are here defined as deeply held ideas or moral concepts about what is good and right and supportive of human flourishing, and which contribute both to personal and to social identity. [14-16] With respect to the former, they are constitutive of the self. With respect to the latter, they are tenets of justice which promote wellbeing (ie: which promote respect for persons, fulfilment of basic human needs, and development of human personality).[17-18] In both cases, although values can be complex, overlapping and opaque, and are therefore often unarticulated or hidden, they are widely held and might be described as "universal" in that recognition of, and some level of adherence to, them transcends culture, a claim supported by their explicit and/or implicit inclusion in both international and domestic instruments.

THE UNESCO DECLARATIONS AND HUMAN DIGNITY

Upon review, it seems fair to suggest that the philosophical-moral foundations of these instruments are neither explicit nor apparently wholly consistent. To the extent that a philosophical foundation is operative, one might label it a human rights foundation, though human rights, from a philosophical perspective, is something of a derivative theoretical approach (ie: flexible, policy-driven and pragmatic).[19] However, as with most instruments within the human rights paradigm, they are founded on, informed by, and protective of, human dignity, a central and self-standing value which sits at the centre of bioethics (eg: dignity is referred to 13 times in the UDHG – Preamble, Articles 1, 2, 6, 10, 11, 12, 15, 21, 24; it is referred to 9 times in the UDB – Preamble, Articles 2, 3, 10, 11, 12, 28).[i]

The dignity invoked, though not specifically defined in either instrument, appears to draw on Kant insofar as it is based on the "unique capacity of human beings to reflect upon their own existence … to perceive injustice … and to exhibit the moral sense that gives expression to ethical principles" (UDB, Preamble, Para. 1),[20] and insofar as it relies on the conviction that: (1) humans should be treated not as means but as ends in themselves; and (2) freedom of rational choice in matters of self-development should be maximised so long as it does not infringe on the equal freedom of others. Given the ubiquitous nature of, and the multiple ways in which, dignity is deployed in these instruments (ie: it is addressed to individuals, groups and the species as a whole, and it has both a constraining and an empowering effect on behaviour), it is perhaps more appropriate to locate and articulate other values that are implicated in the genomic setting and adopted by these instruments.

A preliminary analysis discloses the existence of five "families" of provisions. The five conceptual nodes or categories around which the various Articles orbit are reflective of five notional values, namely (1) autonomy, (2) solidarity, (3) equality, (4) sanctity of life, and (5) democracy. One might go so far as to suggest that these values are dignity dependent. This may be debatable and, ultimately, much might said about their foundation. For present purposes, it seems reasonable to posit that they are, in many ways, supportive of the above conception of dignity, and, perhaps in equal measure, also informed by that value. In any event, a closer examination of the instruments is necessary to illuminate the meaning and scope of these values, which are intended to shape the genomic science of the future.

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[i] Dignity also features prominently in the Universal Declaration of Human Rights (1948), the European Convention on Human Rights (1950) and judicial interpretations of same.

THE UNESCO DECLARATIONS AND OTHER CORE VALUES

Individual Autonomy

Despite references to actions which affect groups, there is an obvious emphasis on the individual in both the UDHG and the UDB. Inevitably, both emphasise the right of freedom of research and its benefit to mankind (UDHG, Article 12(b) [12]; UDB, Preamble, Para. 12 and Article 2(d) [13]).[ii] The one clear limitation they place on this right, however, is that it should never override respect for individual human rights and freedoms and ethical principles (UDHG, Article 10 [12]; UDB, Article 2(d) and 3(2) [13]). They go on to make the following stipulations with respect to research, diagnosis, treatment:

- Genomic or other medical conduct can only be undertaken after full disclosure of the potential risks and benefits of that conduct to the individual (UDHG, Article 5(a) [12]; UDB, Article 6(1) [13]).

- Conduct must be preceded by free, informed and express consent of the person concerned (or, where the person lacks capacity, the consent of his/her representative and only for his/her direct benefit) (UDHG, Articles 5(b) and (e) [12]; UDB, Articles 6 and 7 [13]).

- Personal information (including genetic information) concerning an identifiable individual must be held in confidence and not disclosed for purposes other than those for which it was collected and consented (UDHG, Article 7 [12]; UDB, Article 9 [13]).

- Consent and confidentiality can only be limited by law for compelling public purposes and within the bounds of international law and human rights (UDHG, Article 9 [12]).

- Every individual has the right to decide whether to be informed of results and consequences of genetic tests (UDHG, Article 5(c) [12]).

- Every individual has the right to reparation for damage sustained as a result of genomic interventions (UDHG, Article 8 [12])

- Though cultural diversity is important, it must not be invoked to infringe upon individual rights (UDB, Article 12 [13]).

Although much can be (and has been [21-24]) said about the instruments' lack of specific guidance as to how some of these individual rights are to be realised (particularly in the genomic context where traditional understandings of, and limits associated with, them are less applicable), it is clear that both are heavily influenced by a shared vision of autonomy, a value which, based on the above, encompasses the

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[ii] A right enshrined in the International Covenant on Economic, Social and Cultural Rights (1966), and the UNESCO Recommendation on the Status of Scientific Researchers (1974), and supported in the European context by *Huvig* v. *France* (1990) 12 EHRR 528 (ECHR), and *Niemietz* v. *Germany* (1992) 16 EHRR 97 (ECHR).

idea that individuals, by virtue of being human and therefore having dignity and deserving respect, are entitled to exercise their free will and to govern themselves. This self-rule encompasses physical and legal liberty, and the right to be free from coercive or controlling influences with respect to same.[15, 25-26] For example, individuals who are the subject of conduct are to be informed and empowered, their privacy is to be protected, and actions which are damaging to their autonomy (ie: their physical being or their personal or informational privacy) are actionable. In short, the individual is to be informed and empowered so that s/he can exercise self-rule.

Social Solidarity

Despite strong support for autonomy in both instruments, solidarity (which naturally acts as a counter to the more selfish elements of modern individualism) is also extensively referenced, though again not explicitly defined.

The starting point for an understanding of the value must begin with the UDHG, which, in its Preamble, refers to "a spirit of mutual assistance and concern" and "the intellectual and moral solidarity of mankind", before declaring in Article 1 that the human genome underlies the fundamental unity of all members of the human family, and is, "in a symbolic sense", the "heritage of humanity". This term harkens back to international instruments which characterise space,[27] culture,[28] the moon,[29] and the seabed,[30] as the "common heritage of mankind" warranting special protection and special rules of exploitation. The concept shares with solidarity notions of global community, shared social purpose, common/public resources and intergenerational justice. Though some argue that inclusion of the phrase, "in a symbolic sense", weakens the Article (and the value captured therein),[31] others argue that it merely stresses that the genome is not to be appropriated, and that its value lays not in the commercial realm but in its innate capacity to underline a shared moral obligation to safeguard human existence in the face of the unknowns represented by biotechnologies.[32-33]

Both instruments seek to impose solidarity – with its notions of fraternity, mutual sharing, and assistance of those in need – on individuals, states and other organisations within society.[iii] Both imply a broad and multi-duty definition of the value, which duties must be pursued cooperatively and internationally (eg: Article 18 of the UDHG [12] encourages the fostering of scientific cooperation, particularly as between developed and developing nations; Article 13 of the UDB [13] encourages international cooperation in support of solidarity among humans). Proceeding from the proposition that safeguarding and promoting the interests of present and future generations is import, they articulate a number of issues that should always be considered when acting in the genomic and biomedical fields; stakeholders must:

- recognise that sci-tech developments should promote welfare, and must not infringe human rights and dignity (UDHG, Article 10 [12]; UDB, Preamble,

[iii] Article 13, UDHG, notes the responsibilities of public and private policy-makers. Articles 1(2) and 2(b), UDB, note that, although addressed to states, the UDB is intended to guide individuals, groups, communities, institutions and corporations, public and private. Article 14(1), UDB, notes the shared responsibility of all sectors of society to promote health and social development. Article 23(2), UDB, encourages the participation of numerous stakeholders in bioethics development, and Article 24(3), UDB, notes that individuals, families, groups, communities and states must all promote solidarity. Both instruments caution that they should not be interpreted by individuals, states or groups in such a way as to condone breaches of human rights, dignity or stated principles: see Article 25, UDHG, and Article 28, UDB.

Para. 12 [13]);[iv]

- recognise that sci-tech developments impact on individuals, groups, humankind, and future generations (UDHG, Article 1 [12]; UDB, Articles 2(g) and 16 [13]); [34]

- give due regard to vulnerability (noting that vulnerable populations and developing countries have special needs) (UDHG, Article 17 [12]; UDB, Preamble, Paras. 17 and 21, and Article 8 [13]); and

- give due regard to the interconnectedness of humans and other life forms and the biosphere more generally (UDHG, Article 17 [12]; UDB, Preamble, Paras. 17, 19 and 21, and Articles 2(g) and (h), and 17 [13]).

Additionally, both instruments enumerate the actions required of stakeholders operating in this field. Articles 12(b) and 13 of the UDHG direct scientists to offer relief from suffering and improve the health of individuals and of humankind, and, in doing so, to meet the standards of meticulousness, caution, intellectual honesty and integrity. Between them, these instruments direct states to:

- foster ethical research (including research on the identification, prevention and treatment of genetically-based/influenced diseases, both rare and endemic) (UDHG, Articles 14 and 17 [12]);

- establish multidisciplinary ethics committees independent from political, economic, scientific and medical authorities (UDHG, Article 16 [12]; UDB, Articles 19 and 22(2) [13]);

- disseminate scientific knowledge so that advances can be enjoyed by everyone (UDHG, Article 18 [12]; UDB, Article 24(1) [13]); and

- encourage measures that will enable developing states to share in the benefits of sci-tech research and to build capacity to undertake their own research (UDHG, Article 19 [12]; UDB, Articles 15 and 24(2) [13]), the equitable sharing of benefits accruing from commercial exploitation of the genome having been characterised as the most important human rights issue in the biotechnology setting.[35]

The combined effect of these provisions is to: (1) note that human identity is a multi-factoral and nuanced social construction, and the position of humans in the world is one of shared resources and mutual dependence; and (2) encourage individuals, organisations and states to pursue socially responsible scientific activities which will improve the condition of human health around the world, preserve the biosphere and biodiversity, and materially benefit future generations.[v]

[iv] Also note Article 11, UDHG, which goes on to claim that human reproductive cloning is contrary to human dignity, though it does not explain how or why.

[v] From a jurisprudential point of view, note that the European Court of Human Rights has rejected protecting 'future generations' (embryos) at the expense of existing rights-holders (see *Vo* v. *France*, [2004] ECHR 326 (Grand Chamber)) and rejected protecting future generations and the environment from the dangers of nuclear power absent a specific and imminent danger (see

The solidarity value that is emergent is one grounded in the recognition that individuals are socially embedded. Drawing on principles of compassion and an interest in the well-being of others, it emphasises the collective, the observance of duties and the creation and preservation, through personal and collective action, of a just and decent society. It makes explicit the fundamental unity of humankind, the value of the human community, the importance of active good will toward others, and the promotion of freedom and the capacity in everyone to self-sustain. Generally, it implies a universal duty to contribute to society and to the betterment of life, and to undertake a common effort to protect the heritage of life. Moreover, it is not a purely rhetorical tool denoting a perceived fraternity, but rather an action-oriented value espousing social responsibility and common undertakings.

Equality of People(s)

Both instruments suggest that equality, which relies on beliefs that everyone is of equal worth/value, and that all people should therefore be treated fairly and equitably, constitutes both a moral touchstone and a key objective.

The Preamble of the UDHG "rejects any doctrine of the inequality of men and races", and stipulates that the recognition of genetic diversity "must not give rise to any interpretation of a social or political nature which could call into question the inherent dignity and … equal … rights of all members of the human family". Article 1 then states that the genome underlies the fundamental unity of all members of the human family.[vi] Article 2(a) states that everyone has a right to respect for their dignity (and rights) regardless of their genetic characteristics (ie: even if new technology discloses genetic illness or predisposition to same), and Articles 2(b) and 3 states that genetic determinism, which is rejected as invalid, is to be avoided.[37]

In the genetic context, discrimination can be defined as differential treatment of an individual (or group of like individuals such as family or community) on the basis of real or perceived differences from the "normal" genome. It has also been defined as differential treatment against persons in good health who, because of their genetic make-up, are at increased risk of becoming ill in the future. [38] A common fear is that one's genetic information, which is a personal, immutable characteristic, will be used to define and classify them according to race or other markers such as existence of deficiencies or physical/mental potentialities, and genetic information will therefore become a tool by which to perpetuate existing or create new social, economic or power divisions.[22, 39] Article 6 of the UDHG extends the prohibited grounds for unequal treatment to genetic characteristics.[40]

The UDB builds on the understanding of equality elucidated in the UDHG, noting in its Preamble that all humans, without distinction, should benefit from the imposition of common ethical standards in medicine and bio-research, and that an important component of equality is attention to the position of women. It reiterates the aim of promoting equity, or, more precisely, equitable access to, and rapid sharing

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Athanassoglou et al. v. *Switzerland*, [2000] ECHR 159 (Grand Chamber)). However, the Philippine Supreme Court has allowed a class action on behalf of named plaintiffs and future generations in the context of preservation of public forestland (see *Oposa et al.* v. *Secretary of the Department of Environment & Natural Resources* (1993), 224 SCRA 792 (en banc)).

[vi] The scientific support for human unity includes evidence that there is no biological basis for the concept of race (certainly as we understand and deploy the term), a fact which has been cited as a significant contribution to the elevation of anti-discrimination provisions as undisputed universal norms at international law.[36]

(of the benefits) of, medical, scientific and technological knowledge (UDB, Article 2(f) [12]). Articles 10 and 11 then state that the fundamental equality of all humans in dignity and rights is to be respected so that they are treated justly and equitably, and that discrimination against or stigmatisation on any grounds is forbidden. More specifically, Article 14(2) goes on to state that the highest attainable standard of health (measured by access to water, nutrition, healthcare, decent living conditions and environment, reduction of poverty and illiteracy, and the elimination of marginalisation and exclusion) is a fundamental human right without distinction of race, religion, political belief, economic or social condition, or scientific capability.

Unfortunately, neither "everyone" (Article 2, UDHG [12]) nor "all human beings" (Article 10, UDB [13]) are defined. From a practical point of view, this might be characterised as a significant oversight given the nature of genomic technologies (and related practices like embryonic stem cell research) which give rise to disagreements as to who might be included in these terms.[vii][70] Conversely, it might be conceded that irreconcilable positions on the beginning of personhood, both internationally and within domestic legal jurisdictions, made this a necessary lacunae. In any event, both instruments adopt a robust interpretation of equality, addressing fairness conceptually (through their claims that all people are equal in dignity) and more concretely (through their claims that all people have the right to equal respect and just treatment; not equal treatment *per se*, which might not serve the ends of the value at all, but rather with "equitable" treatment and the swift sharing of benefits so that good health can be realised by all). In short, the conception of equality captured by these instruments appears to comprise two primary elements, namely that, (1) medically and genomically, everyone must be treated appropriately based on what is owed to them due to their personal circumstances, and (2) legally, everyone is equal before and under the law, deserves the equal protection of the law, and is entitled to equal benefit of the law, regardless of personal properties/qualities (including genetic make-up).

Sanctity of Life

Like dignity, sanctity appears to be fully embraced by these instruments; the value gives both instruments context and colours the whole of their content, as evidenced by the recollection in their Recitals of prior instruments specifically addressed to the preservation of life.[viii] However, unlike dignity, which is frequently and explicitly

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[vii] The difficulties presented by the term in juridical settings is exemplified by *Vo* v. *France*, [2004] ECHR 326 (Grand Chamber), wherein the court appeared not to include a 20+ week foetus in that term, and, more recently, by the Korean Supreme Court which ruled that a 42+ week foetus was not a human.[41]

[viii] Both instruments refer to UN Convention on the Elimination of All Forms of Racial Discrimination (1965), UN Convention on the Elimination of All Forms of Discrimination Against Women (1979), and UN Convention on the Rights of the Child (1989). The 1965 convention addresses sanctity in its Preamble and Article 5(b), which articulates a right to security of the person and protection against violence and bodily harm: see http://www.ohchr.org/english/law/cerd.htm. The 1979 conventions addresses sanctity in its Preamble and Articles 3, 5 and 6: see http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm. The 1989 convention addresses sanctity in its Preamble and Articles 2, 3, 6, 9 and 11. Article 6 articulates a right to life and directs states to maximise the survivability and potential of the child, and Article 9 addresses neglect and abuse: see http://www.unhchr.ch/html/menu3/b/k2crc.htm. In addition, the UDHG refers to the UN Convention on the Prevention and Punishment of the Crime of Genocide (1948) (see http://www.unhchr.ch/html/menu3/b/p_genoci.htm), and the Convention on the Prohibition of the

referenced, sanctity is an almost unspoken value which must be found in the character of the instruments; in their penumbra.

The Preambles – with their references to wellbeing and the protection of the human rights and dignity of all people, particularly the vulnerable – speak to this value in a general way. Additionally, both instruments (1) caution against the commercialisation of the human body,[ix] (2) stipulate that biomedical activities must be preceded by a risk-benefit assessment, and (3) highlight the fact that bioscience must be directed toward peaceful and socially useful purposes (UDHG, Articles 5(a) and 15 [12]; UDB, Articles 20 and 21(5) [13]). The UDB adds further to the elucidation of this value, claiming in Article 2(c) the promotion of respect for life as a specific aim, noting in Article 8 that, in advancing science, human vulnerability should be taken into account (eg: the personal integrity of the vulnerable should be protected), and claiming in Article 14(2) that the highest attainable standard of health is a fundamental right and that science and technology should advance access to healthcare, improve living conditions, and reduce poverty. Both instruments also suggest, through their treatment of healthcare and the environment, that genomic advances (and biomedical advances more generally) should contribute to the flourishing of human life. They also both suggest, by their attempt to avoid individual and group marginalisation and the commercialisation of human bodies, that actors should seek to avert harm to human life, even if that hampers future advances. As such, one can discern that the instruments celebrate the phenomenon of life and attach to it special individual and social significance, thereby suggesting that it (human life) demands special legal protection, and this is particularly the case in situations involving vulnerable people or groups.

However, despite the rich history of life-protecting instruments on which they draw, and the few provisions which appear to advance sanctity in the genomic innovation context, there is some ambiguity around the scope of the value embodied. It is unclear whether the sanctity advanced is informed by the idea that human life is intrinsically sacred or, alternatively, that it is specially valuable (ie: it is not obvious whether it is life *qua* life that is valued, a position called vitalism, or whether it is rather the conscious life lived), a matter which has implications for the scope of the value. To generalise, the "sacred" foundation is a religiously-informed one which often elevates life and its preservation to that of an overriding imperative of all people. By contrast, the "specially valued" foundation of sanctity is secularly-informed, and often makes life's special significance contingent on the presence of certain qualities associated with the lived human experience (eg: self-awareness, self-reflection, etc.). Their emphasis on general wellbeing, on science not being advanced at the cost of human rights (which are more commonly enjoyed by the functioning person), on the uniqueness and diversity of individuals (which becomes apparent through interaction), on the importance of culture and cultural diversity (which is

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Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1971) (see http://www.opbw.org/convention/documents/btwctext.pdf).

[ix] Article 4 of the first instrument states that the human genome in its natural state (ie: in its natural environment, being the human body) shall not give rise to financial gains. Article 15(2) of the latter instrument states that benefits (broadly defined) should not constitute improper inducements to participate in research. Presumably, these (partial) bans on commercialisation are based on the idea that money could lead to devaluing the person and endangering life. Given the ability of third parties to gain financially from the human genome through the patenting of genes and gene sequences, the ethical consistency of prohibiting individual gene originators from also gaining can be questioned. Indeed, the IBC subsequently issued an Advice alleging moral grounds for excluding the human genome from patentability.[42]

only relevant to the conscious), and on erecting protections for the vulnerable in particular, doesn't push one definitively toward one interpretation over the other.

(Scientific) Democracy

Perhaps unsurprisingly given the remit of UNESCO and the legislative history of these instruments, both the UDHG and the UDB promote democracy. In this regard, the Preamble of the UDHG explicitly recalls the need to conform to the democratic principles of justice, liberty and peace, before going on to articulate in a variety of Articles the need for cooperation, the free exchange and dissemination of (scientific) information so that all members of society can benefit, and the generation of capacity through international stakeholder consultations and the creation of independent ethics committees. For its part, the UDB highlights the need to respect pluralisms and cultural diversity, and to engage in (international) dialogue so as to foster, *inter alia*, openness, engagement and transparency of decision-making (UDB, Articles 12, 18, 19(d) and 21(4) [13]). Like the UDHG, it also encourages bioethics capacity-building, and the free flow of information (UDB, Articles 23 and 24 [13]). The above suggests that the democratic concepts these instruments seek to encourage are plurality of ideas, facilitation of participation (though not forced participation), transparency of decision-making, and dissemination of outcomes, each of which might be considered essential to the realisation of good science governance by standards of (liberal) modern thinking.[43-44]

Summation: A Plurality of Conflicting Values

The application of dignity in both the UDHG and the UDB to the individual, the family, the community, and the species, gives that value manifold meanings supportive of conflicting consequences, and thereby reduces its utility as an evaluative moral concept. This is not fatal because both instruments evince a strong reliance on a plurality of other shared fundamental values, namely individual autonomy, social solidarity, equality of people(s), sanctity of life and (scientific) democracy, each of which are given substantive content through both the non-operative and substantive provisions.

Although one might subscribe to each of these values simultaneously, they can clearly be contradictory and competitive (ie: circumstances may arise where they cannot all be realised or vindicated in equal measure).[x] This might not have been a problem had the instruments also contained some ranking mechanism or decision-making framework for managing such conflicts. Unfortunately, both are drafted in somewhat absolutist terms, and claims that nothing contained therein should be interpreted as supporting activities contrary to "core principles" (UDHG, Article 25) or "human dignity" (UDB, Article 28), and that limitations of principles should be by law and in the interest of public safety, the protection of public health or the protection of the rights/freedoms of others (UDB, Article 27), offer minimal practical guidance for making decisions as to the appropriate balancing of values.[19, 45]

Nonetheless, it is fairly clear that the combined effect of the moral values advanced, though admittedly reflecting variable degrees of comprehensiveness, is to

[x] For example, within the UDB, note the conviction that the interests of the individual should have priority (Article 3(2)), on the one hand, and the need to promote the interests of future generations and protect public health (a decidedly non-individualistic framework for decision-making)(Articles 2(g) and 27), on the other, and the difficulty of reconciling them.

link genomic knowledge and research to the advancement of human health and wellbeing, and, specifically, with human rights; in essence, to make the preservation of the genome (which contributes to unity and diversity), and the dissemination of advances related thereto (insofar as they improve the human condition), imperatives which all people(s) have a right to demand of all stakeholders active in the field.

CONCLUSIONS: TRANSFERABILITY OF THE "UNIVERSAL" VALUES

It has been suggested that laws emergent from the human rights paradigm, which has become one of the most rhetorically and practically important/influential global legal paradigms in the modern era, are particularly appropriate for managing the ethical/moral concerns raised by genomic research,[46] and both the UDHG and UDB are clearly born of this paradigm and draw on its growing heritage of rights and values. In particular, both instruments erect human dignity as the core ethical value and place it at the centre of all decisions relating to genomic innovation and applications. al But these instruments are more than just ethical guides. Both the UDHG and UDB are legal instruments insofar as they are intergovernmental agreements accompanied by commitments to political action. As such, and because they are intended to have binding legal consequences – if and when they become customary law, and one might note the moral and legal persuasiveness of the Universal Declaration on Human Rights (1948) – they have intrinsic value and relevance.[47-48] Having said that, however, it must be conceded that they are (currently) non-binding, declaratory and, unlike most forms of "hard law", they are pregnant with idealistic and (legally) vague rhetoric which must, certainly in the short term, find voice in other instruments if their underlying values are to be realised (or compelled) in practice.

In fact, if the values which these instruments erect are to truly realise their potential on the ground, they must experience widespread uptake, and not just in the human rights context, although that context is vitally important. Rather, these values must become "subversive" and "leak" into the many and varied fields and genres of law that are both directly and indirectly relevant to the practice and governance of genomics. From an international perspective, that means not only informing the development of human rights through the UN, UNHRC and UNESCO, but also public healthcare policy through the WHO and commercial and trade policy through the WTO and WIPO, the latter arena of which looms so large in the shaping of genomic investigations, technologies and applications. It means not only informing the operation of hard law instruments such as the Convention on Human Rights and Biomedicine (1997),[49] but also the operation of instruments such as the Paris Convention (1883),[50] the TRIPS Agreement (1995),[51] and the Doha Declaration (2001).[52]

In short, if the UDHG and UDB and the moral values they claim as essential to genomics are going to be realised, the commercial arena must represent a site of moral/ethical cohesion and legal enhancement. To realise this, the primary international commercial actors must expand their view of what is "valuable", and they must permit these values to shape both their view of the world and their interpretation and application of their most important legal instruments. Without this cohesion, these values (and therefore the UDHG and UDB) will fail to reach (and therefore influence) a key constituency in the genomic field and will remain rhetorical. As such, the true test for the UDHG and the UDB, which test still lies before them, is whether they and their "universal" values can influence in a real way

the manner in which stakeholders, both public and private, conduct themselves in the for a that really shapes genomics. Admittedly, it will be an uphill battle, but the conceptual and legal mechanisms already exist. For example, see Articles 7 and 27 of the TRIPS Agreement, which inject a moral element into patenting practices, and note the rise in morality-based opposition activity in European patent practices.

Therefore, watch this policy-making space!

ACKNOWLEDGEMENTS

The author would like to acknowledge the assistance of Prof. G. Laurie, Chair of Medical Jurisprudence, University of Edinburgh, and Director of SCRIPT, AHRC Centre for Research on Intellectual Property and Technology Law, and the ongoing support of InnoGen, ESRC Centre for Social and Economic Research in Innovation in Genomics. The author would also like to thank the Referees for their helpful comments.

COMPETING INTERESTS

None declared.

FUNDING

NA

REFERENCES

1 Bennett L. Recurring Dilemmas: The Law's Race to Keep Up with Technological Change. UNSW Research Paper No. 2007-21. 2007. www.austlii.edu.au/cgi-bin/disp.pl/au/journals/UNSWLRS/2007/21.html?query=law%20morality%20biotechnology (accessed 10 Jul 2007).

2 Brownsword R. Ethical Pluralism and the Regulation of Modern Biotechnology. In Francioni F. ed. *Biotechnologies and International Human Rights.* Oxford: Hart Publishing, 2007: 45-70.

3 Honneth A. The Limits of Liberalism: On The Political-Ethical Discussion Concerning Communitarianism. In Wright C. ed. *The Fragmented World of the Social.* NY: NYS Press, 1995.

4 Sandkühler H. Pluralism and the Universality of Rights. 1998. http://www.bu.edu/wcp/papers/law/lawsand.htm (accessed 9 Mar 2007).

5 Habermas J. *Between Facts and Norms.* Boston: MIT Press, 1996.

6 Shavell S. Law Versus Morality as Regulators of Conduct. Am Law & Eco Rev. 2002; 4: 227-257.

7 Raz J. Incorporation by Law. Legal Theory 2004; 10: 1-17.

8 IBC, *Towards a Declaration on Universal Norms on Bioethics – Written Contributions*, SHS/EST/04/CIB-EXTR/INF.1, 25 April 2003, at 33-34.
9 Schauer F. The Social Construction of the Concept of Law: A Reply to Julie Dickson. Ox. J. Legal Studies 2005; 25: 493-501.
10 Ginsberg M. The Enforcement of Morals. Brit. J. Sociology 1961; 12: 65-68
11 Unwin N. Morality, Law and the Evaluation of Values. Mind 1985; 94: 538-549.
12 UNESCO 29th General Conference, 29 C/Resolution 17, 11 Nov. 1997, http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47, at p. 47, subsequently adopted by the UN General Assembly, per UN General Assembly Resolution A/RES/53/152, UN GAOR, 53rd Sess. (1998).
13 UNESCO 33rd General Conference, 33 C/Resolution 36, 19 Oct. 2005, available at http://unesdoc.unesco.org/images/0014/001428/142825e.pdf#page=80, at p. 80.
14 Bruce A. & Tait J. Interests, Values and Biotechnological Risk. InnoGen WP-7. 2003. www.innogen.ac.uk/assets_innogen/dynamic/1118847372616/working-paper-7.pdf (accessed 11 Aug 2007).
15 Harmon S. Regulation of Human Genomics and Genetic Biotechnology: Risks, Values and Analytical Criteria. InnoGen WP-40. 2005. www.innogen.ac.uk/Publications/40-Regulation_of_Human_Genomics_and_Genetic_Biotechnology (accessed 11 Aug 2007).
16 Harmon S. Solidarity: A (New) Ethic for Global Health Policy. Health Care Analysis 2006; 14: 215-236.
17 Waldron J. Particular Values and Critical Morality. Cal Law Rev 1989; 77: 561-589.
18 Raz, J. The Role of Wellbeing. Phil. Persp. 2004; 18: 269-294.
19 For more on how these instruments borrow from the human rights context, see Broussard H. The 'Normative Spectrum' of an Ethically-Inspired Legal Instrument: The 2005 Universal Declaration on Bioethical and Human Rights. In Francioni F. ed. *Biotechnologies and International Human Rights.* Oxford: Hart Publishing, 2007: 97-127.
20 For a critique of the UDB's assumption about humans, see Asai A. & Oe S. A Valuable Up-to-Date Compendium of Bioethical Knowledge. DWB 2005; 5: 216-219.
21 Harmon S. The Significance of UNESCO's Universal Declaration on the Human Genome and Human Rights. SCRIPT-ed 2005; 2: 18-47
22 Andorno R. Human Dignity and the UNESCO Declaration on the Human Genome. 2004. www.ccels.cardiff.ac.uk/pubs/andornopaper.html (accessed 11 Aug 2007)
23 Harris J. & Keywood K. Ignorance, Information and Autonomy. TMB 2001; 22: 415-436.
24 Berger K. Informed Consent: Information or Knowledge? Med Law 2003; 22: 743-750.
25 Beauchamp T. & Childress J. *Principles of Biomedical Ethics*, 4th ed. Oxford: OUP, 1994.
26 Aksoy S. & Elmali A. The Core Concepts of the 'Four Principles' of Bioethics as Found in Islamic Tradition. Med Law 2002; 21: 211-224.
27 UN Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon & Other Celestial Bodies (1966).
28 UN Convention for the Protection of the World Cultural and Natural Heritage (1972).

29 UN Agreement Governing Activities of States on the Moon & Other Celestial Bodies (1979).
30 UN Law of the Sea Convention (1982).
31 Pavoni R. Biodiversity and Biotechnology? Consolidation and Strains in the Emerging International Legal Regimes. In Francioni F. & Scovazzi T., eds. *Biotechnology and International Law*. Oxford: Hart Publishing, 2006: 29-57.
32 Ida R. Human Genome as Common Heritage of Humankind. In Fujiki N. & Macer D., eds. *Bioethics in Asia.* Tsukuba: Eubios Ethics Institute, 1998: 59-63.
33 Francioni F. Genetic Resources, Biotechnology and Human Rights: The International Legal Framework. In F. Francioni, ed. *Biotechnologies and International Human Rights.* Oxford: Hart Publishing, 2007: 3-32.
34 With regard to European approaches to solidarity between generations, see European Commission, Promoting Solidarity Between the Generations, COM(2007) 244, 10 May 2007. http://ec.europa.eu/employment_social/news/2007/may/244_en.pdf (accessed 17 Sep 2007).
35 UN High Commissioner's Expert Group on Human Rights and Biotechnology, "Conclusions", 25 Jan 2002. http://www.unhchr.ch/biotech/conclusions.htm (accessed 26 Jul 2007).
36 Francioni F. Genetic Resources, Biotechnology and Human Rights: The International Legal Framework. Francioni F. ed. *Biotechnologies and International Human Rights.* Oxford: Hart Publishing, 2007: 3-32, at 21.
37 For more on genetic determinism, see Glick D. & Soreg H. Ethics, Public Policy and Behavioural Genetics. Int Med Ass J 2003; 5: 83-86.
38 Reilly P. Public Concern About Genetics. Ann Rev Genomics & H Gen 2000; 1: 485-506.
39 Caplan A. Handle With Care: Race, Class and Genetics. In Murphy T. & Lappe K. eds. *Justice and the Human Genome Project.* Berkeley: U. of Cal. Press, 1994.
40 For more on genetic discrimination, see I. Motoc, Special Rapporteur, *Specific Human Rights Issues: Human Rights and the Human Genome,* E/CN.4/Sub.2/2004/38, 23 July 2004. http://daccessdds.un.org/doc/UNDOC/GEN/G04/155/02/PDF/G0415502.pdf?OpenElement (accessed 17 Sep 2007).
41 Li-Sun J. Supreme Court: Until Labour, the Foetus is Not a Human Being, 12 Jul 2007, Asia News, available at http://www.asianews.it/index.php?l=en&art=9806&size=A (accessed 27 Jul 2007).
42 UNESCO, *Advice of the IBC on the Patentability of the Human Genome*, IBC, 8th Sess., Paris, 14 September 2001. http://portal.unesco.org/shs/en/file_download.php/a31f06b46b1d02ba013e82c6c6217000advice+english.pdf (accessed 17 Sep 2007).
43 For more on liberal tenets of good government, see Burley J. An Abstract Approach to the Regulation of Human Genetics: Law, Morality and Social Policy. In Somsen H. ed. *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents.* Cheltenham: Edward Elgar, 2006: 63-92.
44 For more on the multiplicity of conceptions of democracy, see Collier D. & Levitsky S. Democracy with Adjectives: Conceptual Innovation in Comparative Research. World Politics 1997; 29: 430-451.
45 Selgelid M. Universal Norms and Conflicting Values. DWB 2005; 5: 267-273
46 Andorno R. Biomedicine and International Human Rights Law: In Search of a Global Consensus. WHO Bull 2002; 80: 959-963.

47 Boyle A. Some Reflections on the Relationship of Treaties and Soft Law. ICLQ 1999; 48: 901-913,
48 Andorno R. The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics. 2007. http://www.unesco.de/1507.html?&L=0 (accessed 5 March 2008).
49 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, ETS No. 164, 1997, available at http://conventions.coe.int/treaty/en/treaties/html/164.htm.
50 Paris Convention for the Protection of Industrial Property (1970) available at http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P19_137.
51 Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, Marrakech Agreement Establishing the World Trade Organisation, Marrakech, Morocco, 15 April 1994, available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.
52 WTO Ministerial Declaration, WT/MIN(01)/DEC/1, 20 November 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf.